

## REMARKS

Claim 1 has been amended to incorporate the subject matter of Claim 3 as formerly recited.

Claim 3 has been amended to recite that the composition comprises a proportion of the first compound to the second compound in a ratio of from about 70:30 to about 90:2. Support for the amendment is found in the specification at page 9, lines 15-26.

Claim 24 has been added. Claim 24 depends from Claim 22 and recites that the vehicle comprises a proportion of the first compound to the second compound in a ratio of from about 70:30 to about 90:2. Support for the amendment is found in the specification at page 9, lines 15-26.

Withdrawn Claims 10 and 15 have been amended to depend from Claim 1.

Withdrawn Claim 22 has been amended to recite a coating composition as recited in Claim 1.

Claims 1-20 and 22-24 are pending. Claims 10-20 and 23 are currently withdrawn. Claims 1-9, 22, and 24 are under consideration.

### **Status of Claim 22 as under Consideration:**

The Office Action dated October 5, 2010, the Office had withdrawn the restriction of Claim 22 (Office Action dated October 5, 2010 at last paragraph on page 2). The Office Action dated March 15, 2011 has accordingly considered the patentability of Claim 22 but has listed Claim 22 as being withdrawn from consideration in the Office Action Summary. Correction of the status of Claim 22 in the Office Action Summary as being under consideration is requested.

### **Rejection of Claims 1-9 and 22 under 35 USC §103(a) over Ding (U.S. Patent 7,294,329) in View of Hsu et al. (U.S. Patent 6,340,465) and the Kollidon VA 64 Technical Information ("Kollidon Reference") as Evidenced by Li et al. (U.S. Publication 2002/0026234); Rejection of Claims 1-9 under 35 USC §103(a) over Ding in View of Hsu et al. and the Kollidon Reference as Evidenced by Li et al., and Further in View of Sass (U.S. Patent 6,383,215):**

Because the two rejections listed in the heading are very closely related, Applicants will argue them together.

The two rejections as applied to independent Claims 1 and 22 are traversed because the teachings of Hsu et al. suggest that modifying Ding's coating to have a lubricious surface in the manner of Hsu et al. would prevent the release of any drug contained therein. The proposed

modification by the Office to provide a lubricious surface on Ding's stent therefore contradicts the explicit recitation in the claims that "the vehicle is configured to release the bioactive material" and modifies Ding's coating in a manner that both renders it unsatisfactory for its intended purpose and changes its principle of operation.

The Office has proposed modifying Ding's coating composition to include a polyvinylpyrrolidone-vinyl acetate co-polymer for the purpose of providing a lubricious surface on devices coated with the composition (Office Action dated March 15, 2011 at paragraph spanning pages 5-6). The Office has relied exclusively on Hsu et al. for the putative teaching that including polyvinylpyrrolidone-vinyl acetate copolymer in a coating composition provides a lubricious surface. However, Hsu et al. nowhere teach or suggest that including only polyvinylpyrrolidone-vinyl acetate in a coating composition is sufficient for providing a lubricious surface.

Instead, Hsu et al. teach that at least two components are required for providing a lubricious surface. The required components include a coupling agent and a polyfunctional polymer: "The 'basic' coating compositions of the present invention are prepared by combining the polyfunctional polymer with a crosslinking (coupling) agent, as described herein" (Hsu et al. at column 9, lines 49-51).

Hsu et al. teach that the coupling agent and the polyfunctional polymer form a three-dimensional lattice that entraps other components of the composition in a crosslinked network. The forming of such a crosslinked network by virtue of the coupling agent and the polyfunctional polymer are taught as being necessary for conferring or enhancing the lubricity of the coatings:

...[T]his invention relates to coatings which include coupling agents and polyfunctional polymers which are able to form a crosslinked (or latticed) coating and are capable of entrapping hydrophilic and/or lubricious compounds. **This capacity confers or enhances the lubricious quality of the coatings.** (Hsu et al. at column 2, lines 48-53)

Hsu et al. therefore teach that providing a lubricious surface requires at least adding a coupling agent and a polyfunctional polymer to a coating composition.

Hsu et al. additionally teach that "at least one biocompatible agent" may also be added in the composition for the lubricious coating. Such biocompatible agents are taught as including agents that enhance the lubricity of the coating and/or provide the coating with certain "bioactive" properties. As

alleged by the Office, polyvinylpyrrolidone/vinyl acetate copolymer is taught as an example of a biocompatible agent. Importantly, Hsu et al. teach adding bioactive agents only in combination with the coupling agent and the polyfunctional polymer. See Hsu et al. at column 3, lines 5-11 and 56-61; column 4, lines 10-21 and lines 27-47; column 9, lines 31-35; and elsewhere.

Following the teachings of Hsu et al., modifying Ding's stent to have a lubricious outer surface would require at least adding a coupling agent and a polyfunctional polymer along with the polyvinylpyrrolidone/vinyl acetate copolymer alleged by the Office.

However, adding a coupling agent and a polyfunctional polymer along with a polyvinylpyrrolidone/vinyl acetate copolymer to the composition of Ding would inhibit release of the drug added by Ding. Hsu et al. teach that any biocompatible agent added along with the coupling agent and polyfunctional polymer is stably incorporated into the crosslinked lattice such that it is not released therefrom. See Hsu et al. at section entitled "Incorporating Biocompatible Molecules into Coating Compositions" at column 11, line 42-column 13, line 54. See also Applicants' Response dated January 5, 2011 at second full paragraph on page 9, incorporated herein by reference. Hsu et al. teach that biocompatible agents that are incorporated into the crosslinked lattice include those that confer a pharmacological effect (see Hsu et al. at column 12, line 10-column 13, line 17). Hsu et al. teach that incorporating the biocompatible agent into the crosslinked lattice can be performed by adding the biocompatible agent prior to adding the coupling agent, after adding the coupling agent, or simultaneously with the coupling agent (see Hsu et al. at column 10, lines 9-33). The order in which the components are added does not affect whether the biocompatible agent is entrapped within the matrix. Thus, regardless of whether Ding's drug is added prior to, simultaneous with, or after the lubricious surface-conferring coupling agent and polyfunctional polymer, Ding's drug would be entrapped within the matrix thereby preventing its release.

In sum, modifying Ding to have a lubricious surface in the manner taught by Hsu et al. includes at least adding a coupling agent and a polyfunctional polymer to Ding's composition. The crosslinked network formed by the coupling agent and the polyfunctional polymer, according to the teachings of Hsu et al., would prevent release of any drug added to Ding's composition. Such a modification contradicts the explicit recitation in the claims that "the vehicle is configured to release the bioactive material" (see Claims 1 and 22). It also modifies Ding's coating in a manner that renders it unsatisfactory for its intended purpose and changes its principle of operation, as the

coating of Ding is specifically formulated to release the added drug (Ding at abstract; column 1, lines 8-9; and elsewhere). It is well-settled that a proposal to modify a prior art device in a manner that renders it unsatisfactory for its intended purpose and/or changes its principle of operation is improper in an obviousness rejection. See MPEP §2143.01(V) and §2143.01(VI) and cases cited therein.

The further combination of Ding and Hsu et al. with the Kollidon literature, Li et al., and/or the Sass patent does not cure the fundamental shortcomings of the combination of Ding and Hsu et al. Therefore, for the reasons expressed above, the present obviousness rejection is improper.

The Office has stated that the test for obviousness is not whether the entirety of teachings of Hsu et al. can be literally inserted into the those of Ding but is rather what the combined teachings of the references would have suggested to those of ordinary skill in the art (Office Action dated March 15, 2011 at lines 8-14 of paragraph spanning pages 10 and 11). As outlined above, however, Hsu et al. teach that at least a coupling agent and a polyfunctional polymer are required for conferring lubricity and that these components form a crosslinked lattice that entrap other elements included therewith. By contrast, Hsu et al., alone or in combination with the other cited references do not teach or even suggest that adding a polyvinylpyrrolidone-vinyl acetate co-polymer alone is sufficient for conferring lubricity. Thus, the combined teachings of the references suggest to a practitioner of ordinary skill in the art that conferring lubricity requires including a coupling agent and a polyfunctional polymer and that these components entrap other components within the matrix.

The Office has also stated that “the rejection does not suggest modifying the invention of Hsu et al. but instead modifies that of Ding” (Office Action dated March 15, 2011 at lines 6-7). As outlined above, however, modifying Ding to have a lubricious surface as taught by Hsu et al. modifies Ding in a manner that renders Ding’s composition distinct from the recited composition. If, by contrast, it is proposed to modify Ding to include only a polyvinylpyrrolidone-vinyl acetate co-polymer for providing a lubricious surface, then this indeed modifies the teachings of Hsu et al. and does so in a manner at odds with reference.

Regarding support for the motivation to modify Ding in view of Hsu et al., the Office has stated that “Ding contemplates lubricious polymers as ‘other’ polymers in their coating composition” (Office Action dated March 15, 2011 at lines 1-3 of paragraph spanning pages 5-6). Whether or not this is the case, it is not clear from this alleged contemplation that Ding is open to having a lubricious

surface or that a lubricious surface would be desirable for the Ding's stent. Ding is completely silent regarding a lubricious surface. Furthermore, Ding teaches starch alongside hyaluronic acid. Starch is well-known as a "sticky" polymer. It is not obvious that a practitioner in the art would be motivated to provide a lubricious surface on Ding's stent.

For the reasons outlined above, Claims 1-9 and 22 are not obvious over any combinations of Ding, Hsu et al., the Kollidon Reference, Li et al., and Sass.

Specifically regarding Claim 3 as currently amended, this claim is not obvious over any combinations of Ding, Hsu et al., the Kollidon Reference, Li et al., and Sass because these references do not teach or suggest a proportion of the recited first compound to the recited second compound in a ratio of from about 70:30 to about 90:2.

Applicants submit that Claims 1-9 and 22 are not obvious over any combinations of Ding, Hsu et al., the Kollidon Reference, Li et al., and Sass. Withdrawal of this rejection is requested.

**Rejection of Claims 1, 5-6, 9 and 22 under 35 U.S.C. 103(a) over Whitbourne et al. (U.S. Patent 6,110,483) as Evidenced by DuPont et al. (U.S. Patent No. 5,026,771) and Dhaliwal et al. (2002, *Thermochimica Acta* 391:245-255):**

This rejection has been overcome by amendment of the claims.

Claim 1 has been amended to incorporate the subject matter of Claim 3 as formerly recited. Claim 3 as formerly recited was not subject to this rejection. Therefore, Claim 1 and claims depending therefrom are not subject to this rejection.

Withdrawal of this rejection is requested.

**New Claim**

Claim 24 has been added. Claim 24 depends from Claim 22 and recites that the vehicle comprises a proportion of the first compound to the second compound in a ratio of from about 70:30 to about 90:2. This claim is patentable over the cited prior art of record at least for the reasons stated above for Claim 22. Furthermore, Ding, Hsu et al., the Kollidon Reference, Li et al., and Sass do not teach or suggest either alone or in combination a proportion of the recited first compound to the recited second compound in a ratio of from about 70:30 to about 90:2.

Notice of allowance of Claim 24 is requested.

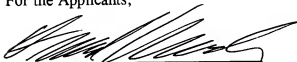
### Rejoinder of Withdrawn Claims

Each withdrawn claim depends from or recites the subject matter of Claim 1. Rejoinder of all withdrawn claims upon allowance of claim 1 is requested.

### Conclusion:

Applicants submit the application is now in condition for allowance.

For the Applicants,



**Daniel A. Blasiole, M.A., Ph.D.**

**Reg. No. 64,469**

**Customer No.: 60961**

**DEWITT ROSS & STEVENS, S.C.**

**2 E. Mifflin Street, Suite 600**

**Madison, Wisconsin 53703-2865**

**Telephone: (608) 395-6758**

**Facsimile: (608) 252-9243**

I certify that this paper is being electronically submitted to the U.S. Patent and Trademark Office via the EFS-Web system on the following date:

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